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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,952	03/06/2006	Ingo Haeberlein	59181US004	8655

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/539,952	HAEBERLEIN ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) *31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-30* is/are rejected.

7)☒ Claim(s) *17-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 17-30 are objected to because of the following informalities: the term "Dental" should be rewritten as "dental". Appropriate correction is required.

Claims 18-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from claims that are cancelled. For purposes of examination, it is assumed that claims 18-21, 23, 24 and 27-30 depend from claim 15, that claim 22 depends from 21 and that claims 25 and 26 depend from claim 24.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "the liberation of the substance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Improper Subject Matter ("Hybrid" Claims)

Claims 19, 21-22 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A single claim which recites both a product and method steps of using that product is indefinite under 35 USC 112, second paragraph. See Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Such claims should also be rejected under 35 USC 101 on the theory that the claim is directed to neither a "process" nor a "machine", but rather embraces or overlaps two different statutory categories of invention set forth under that statute, which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. At 1551.

Instant claims 19-21 and 24 recite both a product (a dental material) and a process requiring active steps as reflected in the phrase "stored in the area". Claims 19, 21 and 24 are thus rejected (along with its dependent claims) on the theory that the claim is directed to neither a "process" nor a "product" exclusively.

For examination purposes the claims are interpreted to read on a product (i.e., a dental material).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19, 21-22 and 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because the hybrid claims are directed to both a product and a process as outlined supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-26 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2002/006820. (US 2004/0029171 is the national stage application for this WO reference and is used for translation purposes).

The current claims are directed to a dental material comprising at least one substance whose antibacterial efficacy is formed in the presence of intraoral microbes.

The reference teaches an invention that relates to a method for analysis and a device for carrying out the method for analysis of saliva and is suitable for the detection of caries-causing and/or periodontitis-causing bacteria found in saliva and/or gum pocket fluid [0001]. The invention includes the use of a device containing a composition which comprises an indicator substance [0011]. The indicator substance includes all substances which are suitable for generating a detectable signal with another substance [0032] such as, *inter alia,* methylene blue and benzofurazan deriatives [0033]. The indicator substances can be bonded covalently to, inter alia, polyethers. The composition of the invention may also include hydrogen peroxide, a known initiator [0133].

Although defined in the reference as indicator substances, it is submitted that when methylene blue and the benzofurazan derivative come into physical contact with the microbe or microbe enzyme in the saliva, then the bacteriostatic or bactericidal efficacy is formed since both methylene blue and the benzofurazan derivative are also antibacterial agents[1,2].

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[1] Kondyukov et al. (Russian Journal of Organic Chemistry; Volume 43, Number 4 / April, 2007:635-636) - disclosing that benzofurazan derivatives possess antibacterial properties (1st page, 1st column, 1st).

Claims 17-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,603,921.

The reference teaches a medicated dental floss with an antimicrobial agent incorporated therein, as a result of the flossing action; the antimicrobial is deposited to the interdental area of the teeth. Fabricating the dental floss comprises dissolving a predetermined amount of chlorhexidine gluconate in a polyethylene glycol base (claim 1). The bacteriostatic/bactericidal efficacy of chlorhexidine is formed when it physically contacts the intraoral bacteria. The substance would naturally be enriched as claimed in claim 19 and 20.

Claims 17-20, 22, 23 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/48766.

Polymerizable dental materials having an antimicrobial effect are provided. These include dental materials such as protective dental varnishes, composites, compomers, fissure sealants, dental cements, dental bonding agents and similar materials, and containing triclosan (abstract).

The dental materials according to the invention preferably contain a matrix of curable or hardenable resin material or materials. Such materials include for example, methacrylate compounds, urethane compounds and the like. Any conventional dental resin or curable dental matrix material is within the scope of the invention. The dental

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[2] US 2006/0177477 - disclosing in [0018] that one photo-oxidant that has been shown by the inventors to

materials may also contain fillers, fluoride, stabilizers, initiators, solvents and other substances conventionally used in dental materials (paragraph bridging pages 6 and 7).

In the curable dental materials described in this invention, the antimicrobial agent triclosan is embedded in a polymeric matrix. This provides the dental materials with a long-lasting antimicrobial effect as the triclosan cannot leach out of these materials quickly (page 7, last paragraph).

Example 3 teaches an example of the invention which comprises 2%, 4%, 6%, 8%, 10% or 15% Triclosan, 4.8 % PENTA (polymerizable material) and 0.2 wt% camphorquinone (initiator).

The substance would naturally be enriched as claimed in claim 19 and 20

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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have excellent antimicrobial properties is methylene blue.

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48766 in view of USP 4,096,241.

The disclosure of the primary reference is outlined *supra*. It does not expressly teach taurolidine.

The secondary reference discloses preparations for the treatment and for prophylaxis of tooth and gum infections (col. 1, ll. 4-6). The preparation effectiveness is due to the unique action of the compounds concerned not only against bacteria but also against the toxins produced by the bacteria. The antimicrobial of choice is taurolidine in view of its extremely low toxicity over long periods of time (col. 1, ll. 65-68).

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *MPEP*

§ 2144.07. Accordingly, it would have been obvious to use taurolidine of the secondary reference as the antimicrobial agent of the primary reference. The motivation would be the reasonable expectation of making the polymerizable dental materials of the primary reference and maintaining antimicrobial properties by using another known antimicrobial agent. Additional motivation would have been to use an antimicrobial known to have low toxicity over long periods of time.

Conclusion

No claims are allowable at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612